

10-04-05

PTO/SB/21 (09-04)

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

| | |
|------------------------|------------------------|
| Application Number | 09/964,273 |
| Filing Date | September 26, 2001 |
| First Named Inventor | Sean Brynjelsen |
| Art Unit | 1615 |
| Examiner Name | P. A. Hawes |
| Attorney Docket Number | CPIFT-5776 (3360-0004) |

ENCLOSURES (Check all that apply)

- | | | |
|---|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below): - Forms PTO/SB/08A and /08B - Check # 21693 for \$180 - 37 cited references - Certificate of Mailing - Return Postcard |
|---|--|---|

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name Cook, Alex, McFarron, Manzo, Cummings & Mehler, Ltd.

Signature

Printed name Raymond M. Mehler

Date October 3, 2005

Reg. No. 26,306

CERTIFICATE OF TRANSMISSION/MAILING

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Signature

Typed or printed name Barbara Gesiakowski

Date October 3, 2005

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PATENT
Attorney Docket No. CPIFT-5776 (3360-0004)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Brynjelsen et al.

Serial No.: 09/964,273

Filed: September 26, 2001

Group Art No.: 1615

Examiner: P. A. Hawes

For: PREPARATION OF SUBMICRON
SOLID PARTICLE SUSPENSIONS
BY SONICATION OF MULTIPHASE
SYSTEMS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA
22313-1450:

1. Transmittal Form PTO/SB/21 (1 sheet);
2. Information Disclosure Statement (3 sheets);
3. Fee Transmittal for FY 2005 in duplicate;
4. Check #21693 for \$180.00;
3. Foreign Patent Documents and Non-Patent
Publications (37 Documents);
4. PTO/SB/08A and /08B (4 sheets);
5. Certificate of Mailing (1 sheet); and
6. Return Receipt Postcard.

Name: Barbara Gesiakowski

Signature: B. Gesiakowski



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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL for FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

Complete If Known

| | |
|----------------------|------------------------|
| Application Number | 09/964,273 |
| Filing Date | September 26, 2001 |
| First Named Inventor | Sean Brynjelsen |
| Examiner Name | P. A. Hawes |
| Art Unit | 1615 |
| Attorney Docket No. | CPIFT-5776 (3360-0004) |

TOTAL AMOUNT OF PAYMENT (\$180.00)

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-1039 Deposit Account Name: Cook, Alex, McFarron, Manzo, et al.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee
☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

| Application Type | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | Fees Paid (\$) |
|------------------|-------------|-----------------------|-------------|-----------------------|------------------|-----------------------|----------------|
| | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | |
| Utility | 300 | 150 | 500 | 250 | 200 | 100 | |
| Design | 200 | 100 | 100 | 50 | 130 | 65 | |
| Plant | 200 | 100 | 300 | 150 | 160 | 80 | |
| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | |

2. EXCESS CLAIM FEES

| Fee Description | Small Entity Fee (\$) | Small Entity Fee (\$) |
|---|-----------------------|-----------------------|
| Each claim over 20 (including Reissues) | 50 | 25 |
| Each independent claim over 3 (including Reissues) | 200 | 100 |
| Multiple dependent claims | 360 | 180 |
| Total Claims | | |
| - 20 or HP = _____ x _____ = _____ | | |
| HP = highest number of total claims paid for, if greater than 20 | | |
| Indep. Claims | | |
| - 3 or HP = _____ x _____ = _____ | | |
| HP = highest number of independent claims paid for, if greater than 3 | | |

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets - 100 = _____ /50= _____ (round up to a whole number) x _____ = _____

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Supplemental Information Disclosure Statement Fee 180.00

SUBMITTED BY

| | | | |
|-------------------|-------------------|---|------------------------|
| Signature | | Registration No. 26,306 (Attorney/Agent) | Telephone 312-236-8500 |
| Name (Print/Type) | Raymond M. Mehler | | Date October 3, 2005 |

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PATENT
Attorney Docket No. CPIFT-5776 (3360-0004)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
Sean Brynjelsen et al.)
Serial No.: 09/964,273)
Filed: September 26, 2001)
Examiner: P. A. Hawes)
Art Unit: 1615)
For: PREPARATION OF SUBMICRON)
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SYSTEMS)

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| NAME <u>Barbara Gesiakowski</u> (TYPED OR PRINTED) |
| SIGNATURE: <u>B. Gesiakowski</u> |

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.97, Applicants hereby call the Examiner's attention to documents listed on the attached forms, which documents may be material to the examination of this application. It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

10/06/2005 HLE333 00000023 09964273

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Copies of the U.S. patents and U.S. patent publications are not enclosed pursuant to the Office's waiving of the requirement under 37 C.F.R. §1.98, paragraph (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication.

No inference should be drawn that any apparatus or method disclosed is equivalent to the subject invention. Also, the citation of the above-discussed documents is not to be construed as an assertion that more pertinent art could not possibly be in existence. Citation of any document herein is not to be construed as an admission that any subject matter disclosed in the document is necessarily within the inventive field of endeavor, that any disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that any disclosure is otherwise necessarily prior art with respect to the instant invention.

Applicants also respectfully reserve the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosure of those documents discussed herein, that may be cited by the Examiner in rejecting a claim in the present patent application.

This Information Disclosure Statement is being submitted after the mailing date of a first Office Action on the merits but before a final action or an action that closes prosecution under 37 C.F.R. § 1.97(c)(2). Consequently, a fee under §1.17(p) is required for the filing of this information disclosure, and is enclosed. If it is determined that an additional fee is required, then authorization is hereby granted to charge Deposit Account 50-1039 any additional fee required.

(A duplicate of this document is enclosed herewith.)

Respectfully submitted,

Date: October 3, 2005

By: 

Raymond M. Mehler, Esq.
Registration No. 26,306
Cook, Alex, McFarron, Manzo,
Cummings & Mehler, Ltd.
200 West Adams St., Suite 2850
Chicago, IL 60606
Telephone: (312) 236-8500
Attorneys for Applicant

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| | | | |
|-------|---|----|---|
| Sheet | 2 | of | 4 |
|-------|---|----|---|

Complete if Known

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|------------------------|------------------------|
| Application Number | 09/964,273 |
| Filing Date | September 26, 2001 |
| First Named Inventor | Sean Brynjelsen |
| Art Unit | 1615 |
| Examiner Name | P. A. Hawes |
| Attorney Docket Number | CPIFT-5776 (3360-0004) |

FOREIGN PATENT DOCUMENTS

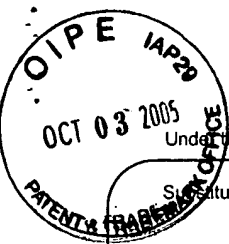
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Signature

Date
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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| | |
|------------------------|------------------------|
| Application Number | 09/964,273 |
| Filing Date | September 26, 2001 |
| First Named Inventor | Sean Brynjelsen |
| Art Unit | 1615 |
| Examiner Name | P. A. Hawes |
| Attorney Docket Number | CPIFT-5776 (3360-0004) |

Sheet

3

of

4

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|---|----------------|
| | 32 | Kinman et al., "Lipid-Drug Association Enhanced HIV-1 Protease Inhibitor Indinavir Localization in Lymphoid Tissues and Viral Load Reduction: A Proof of Concept Study in HIV-2 ₈₇ -Infected Macaques", Journal of Acquired Immune Deficiency Syndrome, 34(4), pp. 387-397 | |
| | 33 | Limoges et al., poster presentation, 11th Conference on Retroviruses and Opportunistic Infections, February 8-11, 2004. | |
| | 34 | Moghimi et al., "Long-Circulating and Target-Specific Nanoparticles: Theory to Practice", Pharmacological Reviews, 53, pp. 283-318, 2001. | |
| | 35 | Nesbit et al., "In Vitro and Animal Models of Human Immunodeficiency Virus Infection of the Central Nervous System", Clinical and Diagnostic Laboratory Immunology, 9(3), pp. 515-524, May 2002. | |
| | 36 | Nottet et al., "HIV-1 Entry into Brain: Mechanisms for the Infiltration of HIV-1 infected Macrophages Across the Blood-Brain Barrier", The Neurology of AIDS, p. 55, 1998. | |
| | 37 | Perno et al., "Relative Potency of Protease Inhibitors in Monocytes/Macrophages Acutely and Chronically Infected with Human Immunodeficiency Virus", The Journal of Infectious Diseases, 178, pp. 413-422, 1998. | |
| | 38 | Sawchuk et al., "Investigation of distribution, transport and uptake of an anti-HIV drugs to the central nervous system", Advanced Drug Delivery Reviews, 39, pp. 5-31, 1999. | |
| | 39 | Solas et al., "Discrepancies between Protease Inhibitor Concentrations and Viral Load in Reservoirs and Sanctuary Sites in Human Immunodeficiency Virus-Infected Patients", Antimicrobiology Agents and Chemotherapy, 47 (1), pp. 238-243, January 2003. | |
| | 40 | Shrayer, et al., "Ceramide, a mediator of apoptosis, synergizes with paclitaxel to induce regression of the L 3.6 human pancreatic carcinoma implanted in SCD1 mice", Journal of Clinical Oncology, Vol. 22, No. 14S, Abstract, 2004:2135. | |
| | 41 | Schroeder et al., "Distribution of Radiolabeled Subvisible Microspheres after Intravenous Administration to Beagle Dogs", Journal of Pharmaceutical Sciences, Vol. 67, No. 4, pp. 504-507, April 1978. | |

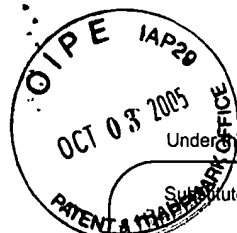
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| Examiner Signature | Date Considered |
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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| First Named Inventor | Sean Brynjelsen |
| Art Unit | 1615 |
| Examiner Name | P. A. Hawes |
| Attorney Docket Number | CPIFT-5776 (3360-0004) |

Sheet

4

of

4

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|--|----------------|
| | 42 | Allen e al., "Large unilamellat liposomes with low uptake into the reticuloendothelial system", FEB, Vol. 223, No. 1, pp. 42-46, 1987. | |
| | 43 | Allen et al., "Effects on the murine mononuclear phagocyte system of chronic administration of liposomes containing drug or lipid A compared with empty liposomes", Can. J. Physiol. Pharmacol., Vol. 65, pp. 185-190, 1987. | |
| | 44 | Graham, D.T., et al., "The Effects of Freezing on Commercial Insulin Suspensions", International Journal of Pharmaceutics, pp. 315-322, 1978. | |
| | 45 | Bender et al., "Efficiency of Nanoparticles as a Carrier for Antiviral Agents in Human Immunodeficiency Virus-Infected Human Monocytes/Macrophases In Vitro", Antimicrobial Agents and Chemotherapy, 40(6) , pp. 1467-1471, June 1996. | |
| | 46 | H. von Briesen, "Controled Release of Antiretroviral Drugs", AIDS Rev., 2, pp. 31-38, 2000. | |
| | 47 | Aquaro, et al., "Macrophages and HIV infection: therapeutical approaches toward this strategic virus reservoir", Antiviral Research 55, pp. 209-225, 2002. | |
| | 48 | Crowe, et al., "The contribution of monocyte infection and trafficking to viral persistence, and maintenance of the viral reservoir in HIV infection", Journal of Leukocyte Biology, Vol. 74, pp. 635-641, November 2003. | |
| | 49 | Fischer-Smith et al., CNS invasion by CD14+/CD16+ peripheral blood-derived monocytes in HIV dementia: perivascular accumulation and reservoir of HIV infection", Journal of NeuroVirology, 7, pp. 528-541, 2001. | |
| | 50 | Igarashi et al., "Macrophage are the principal reservoir and sustain high virus loads in rhesus macaques after the depletion of CD4+ T cells by a highly pathogenic simian immunodeficiency virus/HIV type 1 chimera (SHIV): Implications for HIV-1 infections of humans", PNAS, 98(2), pp. 658-663, January 16, 2001. | |

Examiner
Signature

Date
Considered

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